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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/746,361	11/08/96	ANDERSON D	012712-256

EXAMINER	
GAMBEL, P	
ART UNIT	**PAPER NUMBER**
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DATE MAILED: 01/16/98

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 10/14/97

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s) or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 29-37 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☑ Claim(s) 29-37 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☑ Notice of Reference Cited, PTO-892
☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). 8
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

DETAILED ACTION

1. Applicant's amendment, filed 10/14/97 (Paper No. 10), is acknowledged.
Claims 1-28 have been canceled.
Claims 29-37 have been added.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

3. Formal drawings and photographs have been submitted which fail to comply with 37 CFR 1.84. Please see the form PTO-948 previously sent in Paper No. 7.
Formal figures will be submitted upon indication that this application is allowable.

4. Upon reconsideration of applicant's amended claims filed 10/14/97 (Paper No. 10), which do not recite the 16C10, or 7C10 specific antibodies; the previous rejection under 35 U.S.C. § 112, first paragraph, to satisfy the deposit of biological materials is withdrawn. It is noted that the provision of sequences to entire 16C10 and 7C10 would satisfy the deposit requirement, as indicated by applicant's arguments..

5. Upon reconsideration of applicant's arguments and amended claims, filed 10/14/97 (Paper No. 10); the previous art rejections relying upon inhibitory BB-1-specific B7-specific antibodies has been obviated in view that these antibodies appear to inhibit the binding of B7.1 antigen to CTLA-4. New art rejections which encompass other B7.1-specific antibodies have been set forth herein.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made. Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

8. Claims 29-32 and 37 are rejected under 35 U.S.C. § 102(b) as being anticipated by Razi-Wolf et al. (PNAS, 1992). Razi-Wolf et al. teach the B7-specific antibody 16-10A1. Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. Although the reference is silent about a pharmaceutically acceptable carrier per se, such carriers such as PBS were well known in the art as solvents for storage and immunoassays. Also, the use of supernatants as compositions in experimental models were known at the time the invention was made.

9. Claims 29-32 and 37 are rejected under 35 U.S.C. § 102(b) as being anticipated by Valle et al.(Immunology, 1990). Valle et al. teach the B7-specific antibody 104. Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. Although the reference is silent about a pharmaceutically acceptable carrier per se, such carriers such as PBS were well known in the art as solvents for storage and immunoassays such as flow cytometry and immunoprecipitations analysis referenced in Valle et al.

10. Claims 29-32 and 37 are rejected under 35 U.S.C. § 102(b) as being anticipated by Van Gool et al. (Blood, 1994). Van Gool et al. teach the B7-specific antibody B7-24. Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. Although the reference is silent about a pharmaceutically acceptable carrier per se, such carriers such as PBS were well known in the art as solvents for storage and immunoassays such as blocking in vitro cell-mediated immune responses referenced in Van Gool et al.

11. Claims 29-37 are rejected over Razi-Wolf et al. (PNAS, 1992) OR Valle et al.(Immunology, 1990) OR Van Gool et al. (Blood, 1994) in view of Linsley et al. (U.S. Patent No. 5,434,131) or Linsley et al. (U.S. Patent No. 5,521,288) and art-known procedures and motivation to generate recombinant antibodies (e.g. humanized, chimeric or primatized) for diagnostic and therapeutic regimens as acknowledged on pages 15-20 and 24-27 of the specification (e.g. Newman et al. Biotechnology, 1992).

Razi-Wolf et al. teach the B7-specific antibody16-10A1 which can abrogate T cell activation (see entire document).

Valle et al. teach the B7-specific antibody 104 which is expressed as a B cell activation antigen as well as transformed T cells and lymphoma B cells, which is useful for the study of pathological states linked to lymphocyte activation and the eradication of leukemic cells (see entire document, including the Discussion).

Van Gool et al. teach the B7-specific antibody B7-24 which is able to synergize with cyclosporin A to block alloantigen-induced T cell activation as a means for immunosuppression (see entire document, including the Discussion).

Although these primary references are silent about whether the particular B7 antibody specificities block B7:CTLA-4 interactions per se; all of these references provide motivation to use the particular specificity of said B7-specific antibodies either as immunosuppressants, chemotherapeutic agents or diagnostic tools for activated cells or leukemic cells.

Linsley et al. ('131) or Linsley et al. ('288) all teach the important role of CD28:B7 interactions in regulating immune responses, inhibiting said immune responses with B7-specific antibodies.

In agreement with the specification, it was well known in the art at the time the invention was made to chimerize/primatize/humanize antibodies to have readily available reagents suitable for human diagnosis and therapy and their respective use in primate models. For example, Newman et al. teach the protocols of primatizing antibodies including the use of computer analysis of the instant invention (see entire document). The recombinant techniques and computer analyses of immunoglobulin sequences as taught by the references would have resulted in the same or very nearly the same characteristics of the instant claims since both the references and instant invention use the same techniques, the same antibody specificities and the same goals. The ordinary artisan would have achieved either the same or functional equivalents of the instant B7.1-specific antibodies. Also, note that the claims do not require that one generates the exact same antibody as the instantly disclosed 7C10 and 16C10 antibodies, but rather isolates an antibody that has the same functional characteristics as said antibodies. Also, it is noted that the primary references are not restricted to the BB-1 antibody alone, but rather teach inhibitory B7-specific antibodies that inhibits interactions with CD28-positive T cell with B7 positive cells. The claimed functional limitations are expected properties of the B7-specific inhibitory antibodies. It is noted that the current designation of B7.1 refers to B7 as taught by the references.

One of ordinary skill in the art at the time the invention was made would have been motivated to select B7.1-specific antibodies thereof as diagnostic and therapeutic agents in treating human immunoregulatory disorders. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

12. No claim is allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee can be reached on (703) 308-2731. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1800 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**lila.feisee@uspto.gov**].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Phillip Gambel, Ph.D.
Patent Examiner
Group 1800
Janaury 15, 1998

Phillip Gambel